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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,310

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Jorgen Carlsson

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05/05/2009

WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
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EXAMINER

SWARTZ, RODNEY P

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,310	Applicant(s) CARLSSON ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44, 47.49 and 51-57 is/are pending in the application.
- 4a) Of the above claim(s) 42-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44, 47.49 and 51-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44, 47.49 and 51-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/05, 11/06, 4/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 24 February 2009, is acknowledged. Applicants elect, without traverse, Invention I, claims 1-41, 47, 49 and 51-57, drawn to polypeptides and method of use.

Claims 1-44, 47, 49 and 51-57 are pending. Claims 42-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. Claims 1-41, 47, 49 and 51-57 are pending and under consideration.

Information Disclosure Statement

3. The information disclosure statement filed 29 December 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Sequence Identifiers

4. M.P.E.P. §2422.03, paragraph 9 recites:

37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

5. Page 29, line 37, contains a sequence without the required identifier.

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6. Page 30, line 1, contains a sequence without the required identifier.
7. Page 61, line 32, contains a sequence without the required identifier.
8. Page 63, line 34, contains a sequence without the required identifier.

Specification

9. The disclosure is objected to because of the following informalities:

Page 1, line 25, "e g " should be "e.g.".

Page 7, line 28, "e g " should be "e.g.".

Page 8, lines 2, 10, 22, 26, "e g " should be "e.g.".

Page 9, line 15, "i e " should be "i.e.".

Page 11, line 17, "e g " should be "e.g.".

Page 12, lines 8, 19, 20, "e g " should be "e.g.".

Page 17, line 33, "e g " should be "e.g.".

Page 18, line 25, "e g " should be ",e.g.,".

Page 21, line 6, "e g " should be "e.g.".

Page 35, line 38 to page 36, line 1, delete on of the instances of "according to the manufacturer's protocol".

Page 57, line 30 "100 000" should be "100,000".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-41, 47, 49 and 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a polypeptide which is "related to" another domain of a protein. While the specification teaches examples of "related" polypeptide, the specification does not actually define the metes and bounds of the term. Therefore, it is unclear what is meant by "related to".

12. Claims 1-41, 47, 49 and 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a polypeptide which "corresponds to" another protein. While the specification teaches examples of polypeptides which "correspond to" another protein, the specification does not actually define the metes and bounds of the term. Therefore, it is unclear what is meant by "corresponds to".

13. Claims 1-3, 21, 24-41, 47, 49 and 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a polypeptide with mutations at various positions in the sequence. However, because there is no reference sequence listed, it is unclear how one determines which positions are "substitution mutations".

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14. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims improperly broaden the scope of claim 4. Claim 4 is a polypeptide comprising 1 to about "2" substitutions.

Claim 5 is a polypeptide according to claim 4, comprising 4 to about "20" substitution mutations.

Claim 6 is a polypeptide according to claim 4 comprising up to "4" mutations.

15. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to "A polypeptide according to claim 4 4-9". It is unclear what is meant by this.

16. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a polypeptide whose amino acid sequence is "as set out in" any one of SEQ ID NO:2-79. It is unclear if the claimed polypeptide is a subsequence of one of the listed sequences or "consists of" one of the listed sequences.

17. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claim is drawn to a polypeptide whose amino acid sequence is "as set out in" any one of SEQ ID NO:2-3. It is unclear if the claimed polypeptide is a subsequence of one of the listed sequences or "consists of" one of the listed sequences.

18. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim does not contain a verb.

The claim is drawn to a polypeptide whose amino acid sequence is "as set forth in" SEQ ID NO:1. It is unclear if the claimed polypeptide is a subsequence of SEQ ID NO:1 or "consists of" SEQ ID NO:1.

It is unclear what sequence is utilized to determine the listed positions N3 and others.

19. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what sequence is utilized to determine the listed positions N3A and others.

20. Claims 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is drawn to a polypeptide of claim 1 which comprises additional amino acid residues at either terminal.

Claim 1 is a polypeptide which is related to a domain of SPA in that the sequence of the polypeptide corresponds to the sequence of SPA domain.

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Since neither claim actually lists a sequence, it is unclear what constitutes "additional amino acid residues".

Claims 26-28 also are drawn to the sequence with "additional amino acid residues", but do not clarify the issue seen in claim 25 from which they depend.

21. Claims 28-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is a polypeptide has "optionally further" moiety or moieties. It is unclear what may or may not be included in the claim if the moiety or moieties are "optional".

Claims 29-37 depend from claim 28, but do not clarify the issue.

22. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a phage coat or "fragment thereof". It is unclear what are the metes and bounds of such a "fragment", i.e., size and function.

23. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 depends from claim 1 and improperly broadens the scope of claim 1. It is recommended that claim 38 recite "which further comprises".

24. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The first instance of "ADEPT" must be defined in the claim.

25. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the actual methods of the claimed procedure.

26. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to "positive" and "negative" control tissues slides. However, it is unclear what constitutes a "positive" and a "negative" control tissue slide.

Double Patenting

27. Applicant is advised that should claim 56 be found allowable, claim 57 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The claims are drawn to a kit comprising the same constituents. The recitation of intended use does not distinguish one kit from another.

Conclusion

28. No claims are allowed.

29. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

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If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

May 1, 2009